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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,069	03/30/2001	Kenneth T. Wheeler	9151-6	8239

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EXAMINER

BASI, NIRMAL SINGH

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 10/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/823,069

Applicant(s)

Wheeler et al

Examiner

Nirmal S. Basi

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 30, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1646

DETAILED ACTION

1. *Election/Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 8-9, drawn to isolated polypeptide comprising SEQ ID NO:2, classified in class 530, subclass 350.
- II. Claims 1-7 and 11 drawn to isolated polynucleotide encoding the polypeptide of SEQ ID NO:2, expression vector comprising said polynucleotide, cell comprising said vector and method of preparing said polypeptide using a cell containing said vector classified in class 536, subclass 23.1, for example .
- III. Claims 10, drawn to antibody that specifically binds the protein encoded by the polynucleotide of claim 1, classified in class 530, subclass 387.9, for example.
- IV. Claims 12, drawn to a method for detecting a polynucleotide by hybridizing the complement of the polynucleotide of SEQ ID NO:1, classified in class 435, subclass 6 for example.
- V. Claims 20-21, drawn to isolated polypeptide comprising SEQ ID NO:4, classified in class 530, subclass 350.
- VI. Claims 13-19 and 23 drawn to isolated polynucleotide encoding the polypeptide of SEQ ID NO:3, expression vector comprising said polynucleotide, cell comprising said vector and method of preparing said polypeptide using a cell containing said vector classified in class 536, subclass 23.1, for example .

Art Unit: 1646

- VII. Claims 22, drawn to antibody that specifically binds the protein encoded by the polynucleotide of claim 1, classified in class 530, subclass 387.9, for example.
- VIII. Claims 24, drawn to a method for detecting a polynucleotide by hybridizing the complement of the polynucleotide of SEQ ID NO:3, classified in class 435, subclass 6 for example.
- IX. Claims 25-27, 29-30 drawn to a method for screening for a ligand capable of binding the receptor sequence set forth in SEQ ID NO:2, classified in class 435, subclass -- for example.
- X. Claims 25, 26 and 28-30, drawn to a method for screening for a ligand capable of binding the receptor sequence set forth in SEQ ID NO:4, classified in class 435, subclass 7.1, for example.
- XI. Claims 31 and 32 drawn to a method for determining the proliferative status of cancer cells that express the σ_1 receptor by contacting the cells with detectably labeled σ_1 receptor ligand and a detectably labeled $\sigma_{1\beta}$ receptor ligand, classified in class 435, subclass 7.2.

The inventions are distinct, each from the other because of the following reasons:

The proteins of Invention I are related to the nucleic acids of Invention II by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and

Art Unit: 1646

functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for the processes other than the production of the protein, such as nucleic acid hybridization.

5 The proteins of Invention V are related to the nucleic acids of Invention VI by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and
10 materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for the processes other than the production of the protein, such as nucleic acid hybridization.

 The proteins of Invention I are related to antibodies of Invention III by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and
15 antibody are related due to the necessary steric complementary of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right or in assays for the identification of agonists of the receptor protein.

Art Unit: 1646

The proteins of Invention V are related to antibodies of Invention VII by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary steric complementary of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because
5 the protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right or in assays for the identification of agonists of the receptor protein.

The proteins Inventions I and the methods of Inventions IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can
10 be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins may be used for the production of antibodies of Invention III.

The proteins Inventions V and the methods of Inventions X are related as product and
15 process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins may be used for the production of antibodies of Invention VII.

Art Unit: 1646

The proteins of Invention I are distinct from the methods of Invention IV, VIII and XI wherein the protein of Invention I can neither be used in nor made by the methods of Invention IV, VIII and XI.

5 The proteins of Invention V are distinct from the methods of Invention IV, VIII and XI wherein the protein of Invention V can neither be used in nor made by the methods of Invention IV, VIII and XI.

The methods of Inventions IV, VIII-XI are distinct from each other because they are independent, using separate method steps, active agents and having different effects.

10 The DNA of Invention II are distinct from the methods of Invention VIII-XI wherein the DNA of Invention I can neither be used in nor made by the methods of VIII-XI .

The DNA of Invention V are distinct from the methods of Invention IV and IX-XI wherein the DNA of Invention V can neither be used in nor made by the methods of IV and IX-XI.

15 The products of Inventions II and the methods of Inventions IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides may be used for the production of proteins.

Art Unit: 1646

The products of Inventions VI and the methods of Inventions VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides may be used for the production of proteins.

The products of Invention III are distinct from the method of Invention IV, VIII-XI wherein the products of Invention III can neither be used in nor made by the method of Invention IV, VIII-XI.

The products of Invention VII are distinct from the method of Invention IV, VIII-XI wherein the products of Invention III can neither be used in nor made by the method of Invention IV, VIII-XI.

The products of Inventions I-III and V-VII are distinct because they have distinct functional, chemical and physical properties and are capable of separate use and manufacture.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art, restriction for examination purposes as indicated is proper. A search of the art for Inventions I-XI would not be co-extensive with each other. Because the searches required for these inventions are not co-extensive an examination of the materially different, patentably distinct inventions in a single application would constitute a serious burden on the examiner.

Art Unit: 1646

An election to prosecute one of the groups listed I-XI must be made. Affirmation of this election must be made by applicant in responding to this Office action.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently
5 named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).


Advisory Information


10 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

15 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

20 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi 
Art Unit 1646
25 September 30, 2003


MICHAEL PAK
PRIMARY EXAMINER